

Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

September 12, 2014

Esaote S.p.A. % Ms. Allison Scott Senior Consultant Navigant Consulting, Inc. 9001 Wesleyan Road Suite 200 INDIANAPOLIS IN 46268

Re: Trade/Device Name: 7410 Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: July 31, 2014 Received: July 31, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the 7410 Ultrasound Systems, as described in your premarket notification:

#### Transducer Model Number

SP2730	AL2442	SL1543
SL2325	SL3235	SL3323
SL3332	AC2541	SC3123
SC3421	S2MCW	S5MCW
SHFCW	SE3123	ST2612
SB2C41		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

### DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

#### **Indications for Use**

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.

510(k) Number (if known)	
K142077	
Device Name MyLabGamma (7410)	
Indications for Use (Describe)	
Esaote's Model 7410 is a compact ultrasound system used to perform Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, A Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric a guidance of biopsy and imaging to assist in the placement of needles nerve blocks in Musculoskeletal applications.	dult Cephalic, Small organs, Musculoskeletal (Conventional and and Other: Urologic. The 7410 system provides imaging for
Type of Use (Select one or both, as applicable)	
□ Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - C	ONTINUE ON A SEPARATE PAGE IF NEEDED.
FOR FDA U	SE ONLY
Concurrence of Center for Devices and Radiological Health (CDRH) (	(Signature)
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7410

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N	Z	N	N	N		N	N: 5, 6
Abdominal	Z	N	N	z	Z	z	Z		N	N: 5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Z	N	N	z	Z	z	Z		N	N: 5
Small Organs [1]	Z	N	N		N	Z	N		N	N: 5
Neonatal Cephalic	N	N	N	Z	z	z	Z		Z	N: 5
Adult Cephalic	N	N	N	Z	z	z	N		N	N: 5
Cardiac [2]	Z	N	N	z	Z	z	Z	N	N	N: 5
Transesophageal (Cardiac) [2]	z	N	N	N	Z	N	N	N	N	N: 5
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	N: 5
Transvaginal	N	N	N		N	z	N		N	N: 5
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	N: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Z	N	N		N	N	N		N	N: 5
Musculo-skeletal Superficial [3]	z	N	Z		z	Z	N		N	N: 5
Other (Urological)	N	N	N		N	N	N		N	N: 5
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N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

<sup>[6] 3</sup>D/4D

To be cleared with this submission

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SP2730

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ы	Ь	Ъ	Ь	Ъ	Ь	Ь		Ъ	P: 5
Abdominal	Ь	Ъ	Ь	Ь	Ь	Ь	Ь		Ъ	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ы	Ы	Ь	Ы	Ь	Ь	Ь		Ь	P: 5
Small Organs [1]										
Neonatal Cephalic	Ы	Ы	Ь	Ь	Ь	Ь	Ь		Ь	P: 5
Adult Cephalic	Ы	Ы	Ь	Ь	Ь	Ь	Ь		Ь	P: 5
Cardiac [2]	Ь	Ь	Ь	Ь	Ъ	Ь	Ь	Ь	Ь	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ь	Ь	Ь	Ь	Ь		Ъ	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N. New indication: P. Previously cleared by FDA: E.Added under Annendix E.	Jeared hy	FDA: E:Ad	ded under /	Appendix F	F-					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric [3] Musculo Skeletal - Nerve Block [4] Combined modes are: B+M+PW+CW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

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 $\begin{tabular}{ll} $AL2442$ \\ Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows: $AL2442$ \\ Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows: $AL2442$ \\ Intended use: $AL242$ \\$ 

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ь	Ъ	Ь		Ъ	д	Ь		Ь	P: 5
Abdominal	Ь	Ъ	Ь		Ъ	Ъ	Ь		Ь	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ы	Ы	Ь		Ь	Ъ	Ь		Ъ	P: 5
Small Organs [1]	Ь	Ы	Ь		Ь	Ь	Ь		Ь	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	Ы	Ы	Ь		Ъ	Ь	Ь		Ъ	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ь		Ь	Ь	Ь		Ь	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Д	ы	д		Ъ	Ъ	Ь		ď	P: 5
Musculo-skeletal Superficial [3]	Д	ы	д		Ъ	Ъ	Ь		ď	P: 5
Other (Urological)										
N. New indication: P. Previonsly cleared by FDA: F. Added under Annendix F.	Jeared by	FDA: E:Ado	led under A	nnendix F	æ					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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**SL1543** Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other (specify)
					Doppler	Doppler (PD)	[4]	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal										
Abdominal	Ъ	Ы	Ъ		Ы	Ъ	Ь		Ь	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ь	Ь	Ъ		Ь	Ь	Ь		Ь	P: 5
Small Organs [1]	Ъ	Ы	Ъ		Ы	Ъ	Ь		Ь	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	Ь	d	Ь		Ь	Ь	Ь		Ь	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	d	Ь		Ь	Ь	Ь		Ь	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Ь	А	Ы		Ъ	Ь	Ь		Ь	P. 5
Musculo-skeletal Superficial [3]	ď	ď	Ь		Ь	ď	ď		Ь	P. 5
Other (Urological)										
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by	FDA; E:Add	ded under A	ppendix E	(-)					

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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**SL2325** 

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	B	ы		ম	ਬ	গ্ৰ		E	E: 2
Small Organs [1]	Э	田	ы		ম	ম	ঘ		Ы	E: 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Э	E	E		Е	Э	Э		Э	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Э	Э	Э		E	Э	ম		ъ	E: 5
Musculo-skeletal Superficial [3]	Э	되	ਜ		五	ਜ	ъ		ш	E: 5
Other (Urological)										
M. Mozz in dioction: D. Drozzionaliz ologod	leared by E	by FDA · F· Added under Annendiv F	ad under At	Donordie E						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Under 510K submission K142008

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**SL3235** Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ь	Ъ	Ъ		Ъ	Ь	Ь		Ъ	P: 5
Small Organs [1]	Ь	Ь	Ь		Ь	Ь	Ь		Ь	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ъ		Ь	Ь	Ь		Ь	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	ď	ď	Ь		Ъ	Ъ	Ь		Ъ	P: 5
Musculo-skeletal Superficial [3]	ď	ď	Ь		Ъ	Ъ	Ь		Ъ	P: 5
Other (Urological)										
N. New indication: P. Previonsly cleared by RDA: R:Added under Amendix R	heared hy	FDA: E:Ado	led under A	nnendiy F	r					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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**SL3323** 

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	Ь	Ь	Ъ		Ь	Ь	Ъ		Ъ	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ь	Ь	Ь		Ь	Ь	Ъ		Ь	P: 5
Small Organs [1]	Ь	Ь	Ь		Ь	Ь	Ъ		Ь	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	Ь	Ъ	Ь		Ь	Ь	Ъ		Ь	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ъ	Ь		Ь	Ь	Ь		Ъ	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Ь	д	Ь		Ь	Ъ	ď		Ъ	P: 5
Musculo-skeletal Superficial [3]	д	д	Ы		Ы	Ы	ч		Ь	P: 5
Other (Urological)										
N. New indication: P. Previously cleared by FDA: E.Added under Annendix E.	deared by	FDA: E:Ade	led under /	Appendix F						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

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**SL3332** 

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ь	Ы	Ь		Ь	Ъ	Ь		Ь	P: 5
Abdominal	Ъ	Ь	Ь		Ъ	Ъ	Ъ		Ь	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ъ	Ы	Ъ		Ь	Ь	Ъ		Ъ	P: 5
Small Organs [1]	Ь	Ь	Ь		Ь	Ь	Ъ		Ь	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	Ъ	Ы	Ъ		Ъ	Ъ	Ъ		Ъ	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ы	Ь		Ь	Ъ	Ь		Ь	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Ъ	Д	Ъ		Ь	Ь	Ь		ч	P: 5
Musculo-skeletal Superficial [3]	Д	Д	д		Ь	d	Ы		ď	P: 5
Other (Urological)										
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N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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AC2541 Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ъ	Ъ	Ь		Ь	Ь	Ь		Ъ	P: 5
Abdominal	Ь	Ь	Ъ		Ь	Ь	Ъ		Ъ	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ъ	Ь		Ь	Ь	Ь		Ъ	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Ь	Ъ	Ь		Ь	ď	ď		Ъ	P: 5
Musculo-skeletal Superficial [3]	Ь	Ь	Ь		Ь	ď	ď		Ъ	P: 5
Other (Urological)	Ъ	Ъ	Ь		Ь	Ь	Ь		Ъ	P: 5
N. New indication. D. Dravionsky cleared by FDA. F. Added under Annendiy F.	Jeared by	FDA: E:Ade	ded under A	\nnendix F	۳.					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Previously cleared via k141486

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

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SC3123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	Ь	Ь	Ь		Ь	Ь	Ь		Ъ	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ы	Ы	Ь		Ь	Ь	Ь		Ь	P: 5
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	Ы	Ы	Ъ		Ь	Ь	Ь		Ь	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ъ		Ь	Ь	ď		Ъ	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N. New indication: P. Previously cleared by FDA: E.Added under Annendix E.	deared by	FDA: E:Ade	ded under /	Appendix F	د.					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

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**SC3421** Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ь	Ъ	Ь		Ь	Ь	Ь		Ь	P: 5
Abdominal	Ь	Ь	Ъ		Ь	Ь	Ь		Ь	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ь		Ь	Ь	Ь		Ь	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	Ъ	Ь	Ь		Ф	d	Ь		Д	P: 5
Musculo-skeletal Superficial [3]	Ъ	Ь	Ь		Ь	ď	Ь		Ъ	P: 5
Other (Urological)	ЬЬ	Ъ	Ъ		Ь	Ь	Ь		Ь	P: 5
N. M 1: -4:4: D. D 1	1		Charles aloned by DDA D. Added mades Amendia D	T and one						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Musculo Skeletal - Nerve Block
 Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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# **S2MCW**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	rations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Combined Doppler [4]	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				Ь						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				Ь						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N. New indication: P. Previonsly cleared by FDA: E.Added under Annendix E.	cleared by	FDA: E:Add	led under /	Appendix F						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric[3] Musculo Skeletal - Nerve Block[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

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# **S5MCW**

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Harmonic Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				Ь						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N. New indication: D. Dravicaly cleared by FDA: E.Added under Annandiv E	pleared ht	FDA. F.Ade	Jed under	Annendiy F						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric[3] Musculo Skeletal - Nerve Block[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

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# SHFCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	rations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				Ь						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N. New indication: P. Previously cleared by FDA: F. Added under Annendix F.	cleared by	FDA: E:Ado	hed under	Annendix F						L

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric[3] Musculo Skeletal - Nerve Block[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

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SE3123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ь	Ь	Ь		Ь	Ь	Ъ		Ь	P: 5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	Ь	Ъ	Ъ		Ъ	Ъ	Д		Ь	P: 5
Transvaginal	Ъ	Ъ	Ъ		Ъ	Ъ	Ъ		Ь	P: 5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	Ь	Ь	Ь		Ь	Ь	Ы		Ь	P: 5
N. New indication. B. Bravionsly cleared by FDA. F. Added mader Annendix F.	leared hy	FDA: E:Adc	led under A	Annendix F	ت					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

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**ST2612** Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	erations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	Ь	Ь	Ь	Ь	Ь	Ь	Ь	Ъ	d	P: 5
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
M. Morre indication. D. Decrios decred by DDA. D. Added mades Assessedie D	cleared by	EDA. F.Ad	ded under	Annondiv	ſ					

under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

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**SB2C41** Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	rations			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	Ы	Ь	Ы		Ь	Ь	Ь		Ь	P: 5, 6
Abdominal	Ь	Ь	Ь		Ь	Ь	Ь		Ъ	P: 5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
M. Naw indication: D. Dramonty classed by FDA: F.Added under Arnendiv F	oleaned htt	FDA. F.A.	ded under	Annendiy F						_

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

<sup>[1]</sup> Small Organs includes Breast, Thyroid and Testicles

<sup>[2]</sup> Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

<sup>[5]</sup> Compound Imaging (Mview)

<sup>[6] 3</sup>D/4D

### **Traditional 510(k) Summary**

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

#### **Submitter Information**

Esaote S.p.A. Via di Caciolle 15 Firenze, Italy 50127

Contact Person: Allison Scott

317.228.8719

allison.scott@navigant.com

Date: July 31, 2014

807.92(a)(2)

#### **Devices**

Common Name: Ultrasound Imaging System

Trade Name: 7410 Ultrasound System

Classification Name(s): Ultrasound Pulse Doppler Imaging System 892.1550

Ultrasound Pulse Echo Imaging System 892.1560 Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

### **Predicate Device(s)**

Device	Owner	510(k)
7400	Esaote	K111302, K132231,
		K132466
6420	Esaote	K141486
	Europe	

510(k) Submission 7410 System Esaote, S.p.A.

807.92(a)(4)

#### **Device Description**

Model 7410 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operations are: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D. 7410 is equipped with a LCD color display where acquired images and advanced image features are shown. 7410 system can drive Phased, Convex, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes). On 7410 system the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. 7410 system is equipped with wireless capability. Model 7410 has been designed to be powered by battery.

7410 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

#### **Intended Use**

Esaote's Model 7410 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric and Other: Urologic. The 7410 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

#### **Technological Characteristics**

7410 system employs the same fundamental technological characteristics as its predicate devices.

7410 model is substantially equivalent to Esaote 7400 model cleared by FDA via K111032, K132231, K132466 and to Esaote Europe 6420 cleared by FDA via K141486.

- Clinical uses for which Esaote 7410 system is designed is equivalent to those of Esaote 7400 model, cleared via K111302, K132231 and K132466 and to those of Esaote Europe 6420 cleared by FDA via K141486.
- Esaote 7410 system is designed to meet the IEC60601-1.
- Esaote 7410 system is designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 7410 system provides an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- Esaote 7410 and 7400 and Esaote Europe 6420 systems provide similar measurements and analysis package.

- Esaote 7410 and 7400 and Esaote Europe 6420 systems have digital storage capabilities, including network connectivity.
- Esaote 7410, equipped with wireless capability, is substantially equivalent to 7400 cleared for wireless capability via K111302, K132231 and K132466.
- Esaote 7410, designed to be powered by battery, is substantially equivalent to 7400 cleared for battery powering via K111302, K132231 and K132466.

807.92(b)(1)

#### **Summary of Non-Clinical Tests**

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 6060 1-2-37
- NEMA UD-3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

#### **Summary of Clinical Tests**

No clinical tests were performed.

807.92(b)(3)

#### Conclusion

7410 system is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.